



UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/217,780 03/25/94 WOZNEY

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LEGAL AFFAIRS DEPARTMENT
GENETICS INSTITUTE INC
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EXAMINER

JACOBSON, D

ART UNIT

PAPER NUMBER

14

1814

DATE MAILED:

01/17/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 9/25/95 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 42-54 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 1-41 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 42-54 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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Claims 42-54 are pending in the instant application. Claims 29-41 have been cancelled. The Information Disclosure Statement of 9/21/95 has been considered.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 42-43 are rejected under 35 U.S.C. § 101 because the claims are directed toward non-statutory subject matter.

Claims 42-43 are drawn to DNA molecules comprising isolated DNA sequences. The claims include any DNA molecule comprising the particular sequences, including naturally-occurring DNA molecules, such as chromosomes. The claims are deemed to encompass non-statutory subject matter.

In the absence of the hand of man, naturally occurring nucleic acid sequences are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Additionally, mere purity of a naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui, 156 USPQ 426 (1966). However, when purity results in a new utility, patentability is considered. Merck Co. v. Chase Chemical Co., 273 F. Supp. 68 (1967). Filing of evidence of a new utility imparted by the increased purity of the claimed invention and amendment of the claims to recite a purity limitation, if supported by the specification, is suggested to obviate this rejection. Applicant should point to the basis in the specification for any amendment to the claims.

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This rejection may be overcome by amending the claims to read, "An isolated and purified DNA molecule consisting of the sequence of SEQ ID NO. 1," or the like.

Claims 46-49 and 52 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to the disclosed nucleic acid sequences. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Claim 46 is drawn to a nucleic acid molecule that is an allelic variant of the sequence of SEQ ID NO. 1 or an equivalent degenerate sequence thereof. Claim 46 encompasses any variant of the disclosed V1-1 gene encoding a protein that has the ability to induce tendon/ligament formation. The specification does not disclose variants of the V1-1 gene. Due to the many possible variant sequences and the lack of guidance set forth by the specification regarding other possible variants, it would require undue experimentation for one of skill in the art to isolate, identify, and screen for activity all of the possible allelic variants and degenerate sequences encompassed by the claims. Claims 46-49 and 52 are deemed to be beyond the scope of the enabling disclosure.

Applicants traverse the previous rejection of claims 33-36 and 39 and assert that recitation of "allelic variant" in new claims 46-49 and 52 overcomes the previous rejection. Applicants

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assert that the term "allelic variant" is well understood in the art. Applicants argue that one of skill would expect such DNA sequences would encode active proteins. These arguments and the amendments have been fully considered but are not deemed to be persuasive.

The term "allele" means one of several alternate forms of a gene. An allelic variant is any alternate form of a gene, and includes many different mutations. Alleles may display different phenotypes. The claims, which are drawn to allelic variants of SEQ ID NO. 1, may include many different genes. It is not known what type(s) of variants are encompassed or excluded by the claims. Due to the breadth of the claims and the lack of guidance set forth by the specification regarding variants of the disclosed sequence, it would require undue experimentation for one of skill in the art to identify all of the variants that are encompassed by the claims. Claims 46-49 and 52 are deemed to be beyond the scope of the enabling disclosure.

Claims 42-45, 50, 51, 53, and 54 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 42 and 43 are indefinite in their recitation of "from nucleotides" because this wording is awkward. It is suggested

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that applicants amend the claims to read "consisting of nucleotides....to....of SEQ ID NO.".

Also, in claim 43 the phrase "encoding for" is awkward. The art-accepted wording is "encoding" or "coding for", either of which would be appropriate.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 46-49 and 52 are rejected under 35 U.S.C. § 102(a) as being anticipated by Neidhardt et al. (WO 93/16099).

Neidhardt et al. describe the human MP52 protein that is related to the TGF-beta family of proteins. The reference describes the DNA sequence encoding MP52 and expression thereof by recombinant means. The protein of Neidhardt et al. and the DNA sequence encoding it are 80% homologous to applicants' V1-1 protein. The instant claims include any allelic variant of the disclosed V1-1 protein and include the protein described by Neidhardt et al.

Applicants traverse the previous rejection over Neidhardt et al. on the grounds that one of skill would not consider the MP52 protein to be an allelic variant of applicants' V1-1 protein.

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Applicants point out the specific differences between the MP52 and V1-1 proteins. These arguments and the new claims have been fully considered but are not deemed to be persuasive.

As discussed above, an allelic variant is an alternate form of a gene. It may include any type of alteration of the gene, and may include a different phenotype. Applicants have not limited the claims to a particular type(s) of variation and the claims are deemed to include any variant of the disclosed gene. Because the MP52 and V1-1 protein are about 80% homologous, they may be considered, in the broadest sense, allelic variants of each other. Applicants have not provided evidence that MP52 does not have the same activity as the disclosed V1-1 protein. This rejection may be overcome by a showing that MP52 does not induce tendon or ligament formation or by limiting the claims to the disclosed sequences. Claims 46-49 and 52 are deemed to be anticipated by Neidhardt et al.

Claims 42-54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13, 22, and 23 of copending application Serial No. 08/333,576. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to DNA molecules encoding the V1-1 protein, vectors and host cells comprising said

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DNA molecules, and methods of producing V1-1 by recombinant means. The claims are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 42-54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33, 22, and 23 of copending application Serial No. 08/362,670. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to DNA molecules encoding the V1-1 protein, vectors and host cells comprising said DNA molecules, and methods of producing V1-1 by recombinant means. The claims are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); In re Van Ornam, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dian C. Jacobson whose telephone number is (703) 308-2973. The examiner can normally be reached Monday-Thursday 8:00 to 5:00. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at (703) 308-4216. The FAX number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Dian Jacobson
DIAN C. JACOBSON
PATENT EXAMINER
GROUP 1800